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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,510	11/24/2003	Richard D. Gresham	2877	4596

7590 12/23/2008  
Kimberly V. Perry  
U.S. Surgical  
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Norwalk, CT 06856

EXAMINER
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MENDOZA, MICHAEL G

ART UNIT	PAPER NUMBER
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3734

MAIL DATE	DELIVERY MODE
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12/23/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/720,510	<b>Applicant(s)</b> GRESHAM ET AL.	
	<b>Examiner</b> MICHAEL G. MENDOZA	<b>Art Unit</b> 3734	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 December 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-26 and 31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-26 and 31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/9/2008 has been entered.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-3, 7-9, 11, 12, 17-20, 23-25, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Delago 5827227 in view of Wenstrom, Jr. 5911714.

4. Delago teach a sheath system for enabling access through an opening in the body of a patient, the sheath system comprising: a dilation assembly having a radially expandable tubular sheath defining a lumen having a first cross-section area when in a non-expanded condition, a handle assembly, the handle assembly defining an aperture formed therein, and a first thread defined on the handle in the aperture thereof, an expansion assembly including a tubular member defining a lumen having a second cross-sectional area which is larger than the first cross-section area of the tubular

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sheath of the dilation assembly and having an outer surface defining a second thread, the second thread being arranged for engaging the first thread. It should be noted that Delago fails to teach wherein the second thread is formed along substantially an entire length of the tubular member.

5. Wenstrom, Jr. teaches an assembly with a common thread 225 formed along substantially an entire length of the assembly. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the assembly of Delago to include the second thread along substantially an entire length in view of Wenstrom, Jr. to firmly set the assembly in tissue (col. 9, lines 44-49).

6. Delago/Wenstrom teaches the sheath system according to claim 1, further comprising an introducer sized for receipt in the lumen of the radially expandable sheath; wherein the tubular member of the expansion assembly is configured and dimensioned to be removably received within the aperture formed in the handle assembly; wherein the shaft of the introducer is removably receivable within the lumen of the tubular sheath; wherein the distal advancement of the tubular member of the expansion assembly results in radial expansion of the tubular sheath; a seal at the proximal end of the expansion assembly; a dilator; wherein a distal end of the dilator is tapered.



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8. Claims 1-9, 11, 12, 14, and 15-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dubrul et al. 6080174 in view of Delago in further view of Wenstrom, Jr.

9. Dubrul et al. teaches Delago teach a sheath system for enabling access through an opening in the body of a patient, the sheath system comprising: a dilation assembly having a radially expandable tubular sheath defining a lumen having a first cross-section area when in a non-expanded condition, a handle assembly , the handle assembly defining an aperture formed therein; and an expansion assembly including a tubular member defining a lumen having a second cross-sectional area which is larger than the first cross-section area of the tubular sheath of the dilation assembly. It should be noted the Dubrul et al. fails to teach first and second threads.

10. Delago teaches a device a system using common first and second thread for attaching separate components of the system together (col. 4, lines 4-9). Therefore it would have been obvious to combine the first and second threads of Delago with the sheath system of Dubrul et al. to securely engage the dilation assembly with the expansion assembly and prevent pre-mature separation.

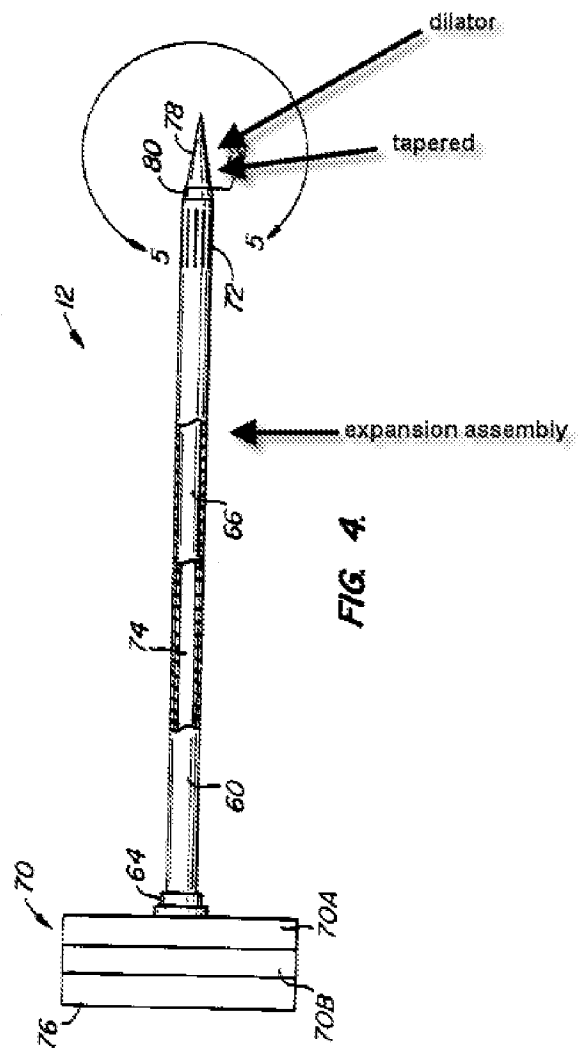
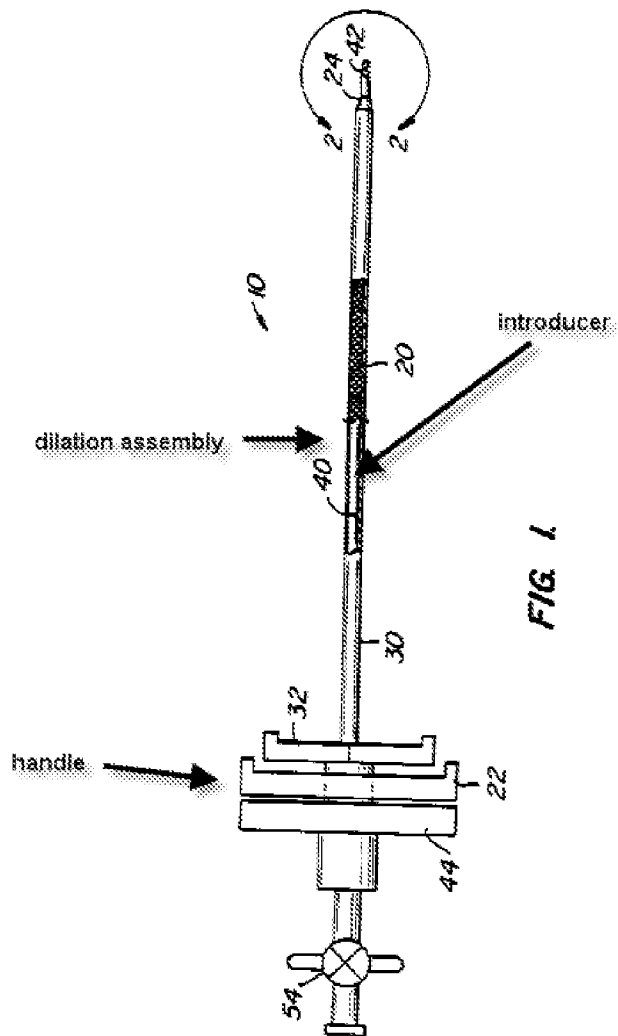
11. It should also be noted that Dubrul/Delago fails to teach wherein the second thread is formed along substantially an entire length of the tubular member.

12. Wenstrom, Jr. teaches an assembly with a common thread 225 formed along substantially an entire length of the assembly. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the

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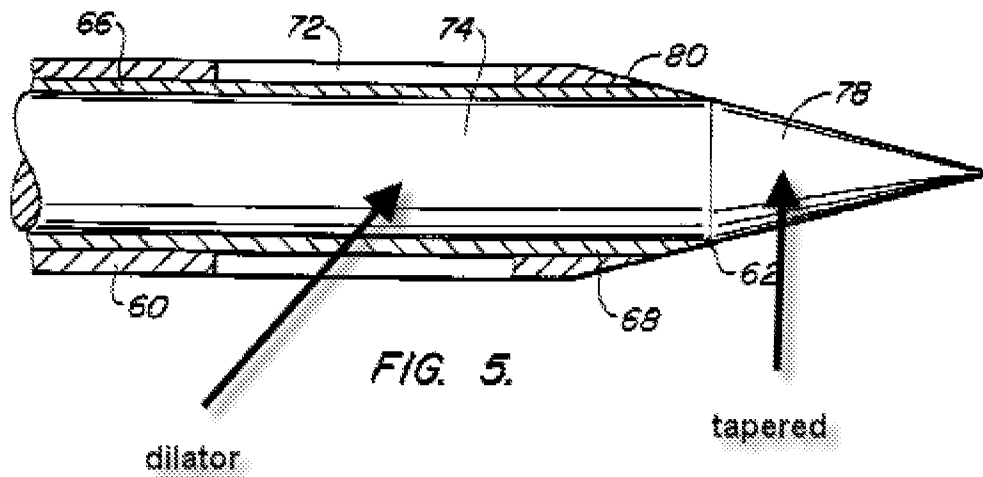
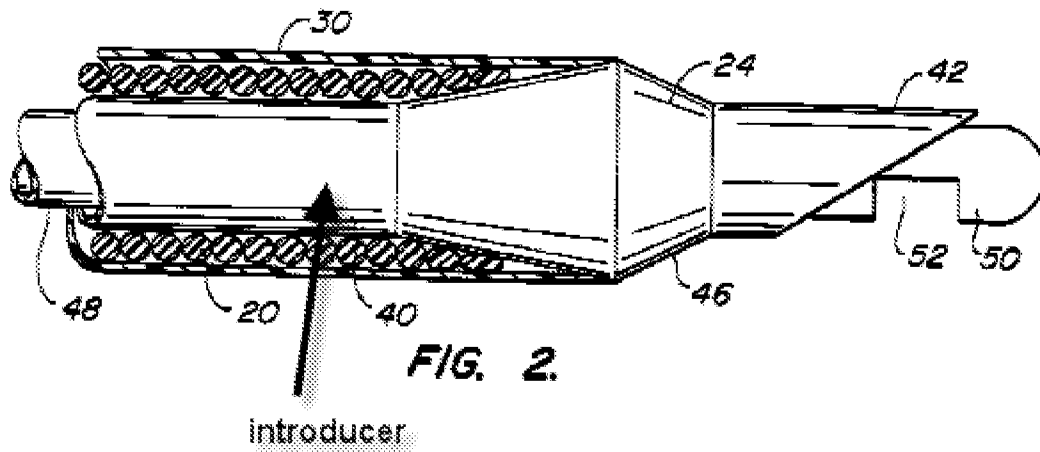
assembly of Delago to include the second thread along substantially an entire length in view of Wenstrom, Jr. to firmly set the assembly in tissue (col. 9, lines 44-49).

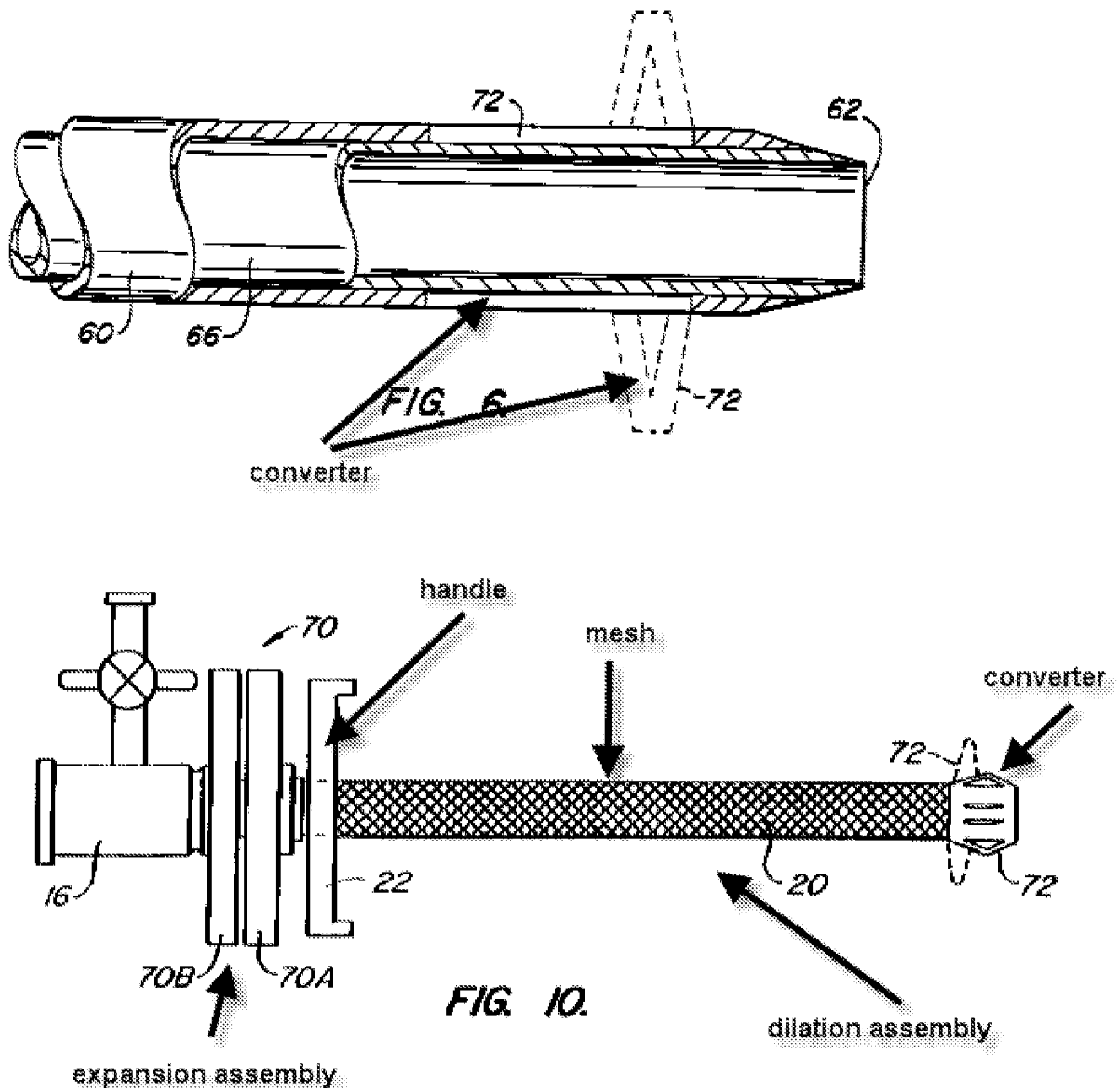
13. Dubrul/Delago teaches the sheath system according to claim 1; further comprising an introducer sized for receipt in the lumen of the radially expandable sheath; wherein the tubular member of the expansion assembly is configured and dimensioned to be removably received within the aperture formed in the handle assembly; wherein the tubular sheath of the dilation assembly comprises a mesh of individual filaments; wherein the filaments are elastic so that radial expansion of the tubular sheath causes axial shortening of the tubular sheath causes axial shortening of the tubular sheath; wherein the tubular sheath comprises a tubular braid of individual filaments; wherein the shaft of the introducer is removably receivable within the lumen of the tubular sheath; wherein the distal advancement of the tubular member of the expansion assembly results in radial expansion of the tubular sheath; seal at the proximal end of the expansion assembly (as taught by Delago); a dilator; wherein a distal end of the dilator is tapered; wherein the dilator has a length such that when the dilator is received with the lumen of the tubular member, the tapered distal end thereof extends beyond a distal end of the tubular member (col. 8, lines 34-38); and a converter.





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14. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Delago/Wenstrom or the combination of Dubrul/Delago/Wenstrom.

15. The above references disclose the claimed invention except for wherein the seal is made from at least one of an elastomeric polymeric material and polyisoprene. It

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would have been obvious to one having ordinary skill in the art at the time the invention was made to use the claim materials, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use a matter of obvious design choice. *In re Leshin* , 125 USPQ 416.

Therefore it would have been obvious to one having ordinary skill in the art to use an elastomeric polymeric material and polyisoprene as a matter of design choice, since Delago has broadly disclosed an elastic seal (col. 4, lines 12-14).

16. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dubrul/Delago/Wenstrom as applied to claims 1-9, 11, 12, 14, and 15-26 above, and further in view of Frova et al. 6767355.

17. Dubrul/Delago/Wenstrom teaches the sheath system according to claim 12. However, Dubrul/Delago fails to teach wherein the distal end of the dilator defines threads.

18. Frova et al. teaches a dilator with common threads at the distal end for anchoring in tissue (col. 2, lines 38-40). Therefore it would have been obvious to one having ordinary skill in the art to include the threaded distal end of Frova et al in the device of Dubrul/Delago to secure the dilator to tissue to prevent unwanted movement.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL G. MENDOZA whose telephone number is (571)272-4698. The examiner can normally be reached on Mon.-Fri. 9:00 a.m. - 5:00 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. G. M./  
Examiner, Art Unit 3734

/Todd E Manahan/  
Supervisory Patent Examiner, Art Unit 3731